



DOCKET NO.: 200427US0 CONT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

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OCT 10 2002  
TECH CENTER 1600/2900

IN RE APPLICATION OF :  
Claudio CAVAZZA : EXAMINER: G. KISHORE  
SERIAL NO: 09/777,874 :  
FILED: FEBRUARY 7, 2001 : GROUP ART UNIT: 1615

#13

FOR: PHARMACEUTICAL COMPOSITION COMPRISING CARNITINE OR  
ALKANOYL L-CARNITINE FOR THE PREVENTION AND TREATMENT OF  
DISEASES BROUGHT ABOUT BY LIPID METABOLISM DISORDERS

PETITION UNDER 37 C.F.R. 1.181

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

Applicants hereby petition the Commissioner under 37 C.F.R. 1.181 to invoke supervisory authority to have the Declaration under 37 C.F.R. 1.132 fully considered. This Declaration was timely filed on January 2, 2002 prior to the Final Rejection. However, specific aspects of this Declaration have not been fully considered or addressed. The Applicants respectfully request that the Office address points A, B and C below.

A. The Applicants request that the written record reflect that the Office accepts the T-test as a conventional test used to determine the statistical significance of differences between compared groups. The attached pages from a statistics review primer show the conventional nature of the T-test. Alternatively, if the Office does not accept the T-test as a valid test of the statistical significance between groups, the Applicants request that it explain why it does not accept the T test and specifically explain why T test results are insufficient to show

statistically significant differences between groups, see MPEP 716.01 (8<sup>th</sup> edition, page 700-215, bottom of second column).

B. If the Office agrees that the T test is a conventional test of statistical significance, then the Applicants respectfully request that it indicate the T-test scores indicated in Tables 2, 4 and 5 of the Declaration filed January 2, 2002 show statistically significant differences between the groups receiving hydroxycitric acid alone, or acetyl-L-carnitine alone, and groups receiving the combination of hydroxycitric acid and acetyl-L-carnitine as shown in Tables 2, 4 and 5 of the Declaration. Alternatively, the Applicants respectfully request that the Office provide an explanation of why the T-test scores reported for Tables 2, 4 and 5 do not show statistically significant differences between the groups compared. For instance, while the Official Action, mailed March 6, 2002, indicates that the Office did not consider there to be significant synergistic differences between groups, see page 3, last five lines-page 4, lines 1-5. This Official Action concludes that only an "additive effect" is achieved based on the reported standard deviation. However, the Office did not explain what statistical method for determining the significance of differences between samples was used to conclude that only an "additive effect" was achieved or why when the standard deviation was considered only an additive effect was shown. Moreover, the Official Action did not address whether or not the Office considers the T-test scores reported in the Declaration indicative of statistically significant differences between groups.

C. Lastly, if the Office accepts the T-test scores shown in Tables 2, 4 and 5 of the Declaration as showing statistically significant differences between the compared groups, then the Applicants respectfully request that the Office indicate that a synergistic effect is observed for groups receiving the combination of acetyl-L-carnitine and hydroxycitric acid, compared to groups receiving only hydroxycitric acid or only acetyl-L-carnitine. For the convenience of the Office the Table below summarizes the results reported in the Declaration

filed January 2, 2002. Synergistic Results are shown in **bold** font.

Summary of Experimental Data of Tables 2, 4 and 5

Table 2: Body Weight Increase

	<u>Level</u>	<u>Reduction</u>	<u>%</u>
Control (no acetyl-L-carnitine or HCA)	62.8	-----	
Acetyl-L-carnitine only:	60.4	-2.4	3.8
HCA only:	46.6	-16.2	25.8
Combination of acetyl-L-carnitine and HCA:	31.6	<b>-31.2</b>	49.9

Table 4: Triglyceride level

Control (no acetyl-L-carnitine or HCA)	195.8	-----	
Acetyl-L-carnitine only:	191.2	-2.4	1.2
HCA only:	170.6	-25.2	12.9
Combination of acetyl-L-carnitine and HCA:	120.4	<b>-75.4</b>	38.5

Table 5: Cholesterol level

Control (no acetyl-L-carnitine or HCA)	270.5	-----	
Acetyl-L-carnitine only:	266.7	-3.8	1.4
HCA only:	196.6	-73.9	27.3
Combination of acetyl-L-carnitine and HCA:	150.5	<b>-120.0</b>	44.4

The Applicants attach herewith a copy of the Declaration filed January 2, 2002 and a copy of pages from a primer on statistics explaining the T test.

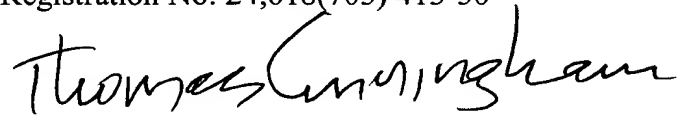
Favorable consideration of this Petition and written acknowledgment of points A, B and C above is respectfully requested.

No petition fee is believed due. However, in the event any variance exists between the required petition fees and this amount, please charge or credit the difference to our Deposit Account No. 15-0030.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

Norman F. Oblon  
Attorney of Record  
Registration No. 24,618(703) 413-30



Thomas M. Cunningham, Ph.D.  
Registration No. 45,394

Attachments: Declaration under 37 C.F.R. 1.132 filed January 2, 2002  
Univariate Inferential Tests, Chapter 7, CliffsQuickReview Statistics

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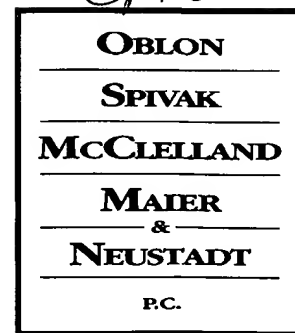
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Filing Date: February 7, 2001

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THE PREVENTION AND TREATMENT OF  
DISEASES BROUGHT ABOUT BY LIPID  
METABOLISM DISORDERS

Group Art Unit: 1615

Examiner: G. Kishore

SIR:

Attached hereto for filing are the following papers:

**Petition Under 37 C.F.R. 1.181 and  
Attachments (Copy of Declaration under 37 C.F.R. 1.132 filed January 2, 2002  
Cliff's Quick Review Statistics, Chapter 7)**

Our check in the amount of \$0.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

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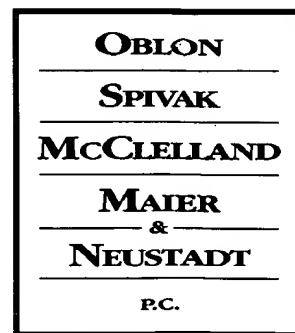
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